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KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER	
FORMAN, BETTY J	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 04/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/782,588	KAIN ET AL.	
	Examiner	Art Unit	
	BJ Forman	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 January 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6,7,10-12,18-25 and 27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 6-7 10-12 18-25 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 14 January 2004 has been entered.

Status of the Claims

2. This action is in response to papers filed 14 January 2004 in which claims1-4, 10-12, 18-20 were amended. All of the amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 30 October 2003 are withdrawn in view of the amendments. All of the arguments have been thoroughly reviewed but are deemed moot in view of the amendments, withdrawn rejections and new grounds for rejection. New grounds for rejection are discussed.

Claims 1-4, 67-, 10-12, 18-25 and 27 are under prosecution.

Additional Comments

3. The claims have been amended to recite "first and second assay locations separated from each other by a physical border". Applicant states on page 6 of the response that the claimed physical border, as defined in the specification, as "a location on a substrate that is physically separated from other regions on the substrate." (page 10, lines 2-3). Applicant further states that the "separation can be any type of border between assay locations. For example, the separation **can** be a partition or a spacing between assay locations sufficient at least to distinguish one from the other. Thus it is clear from the specification that "spacing" is a type of separation, as opposed to a type of "border."'"

Applicant's interpretation of the specification is acknowledged. Applicant appears to be suggesting that the claimed "physical border" be interpreted narrowly as a partition or spacing differing from a separation between the microsphere. However, claims are not so limited. The clams merely recite a "physical border". The specification does not define or describe a "physical border". The phrase is not deemed indefinite because one of ordinary skill would understand the phrase. The phrase is not deemed new matter because the specification (page 10) describes borders and describes physical separations. Hence, the phrase, interpreted broadly, encompasses any physical spacing between microspheres.

For purposes of examination, the claims are interpreted broadly and narrowly as discussed below.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-4, 6-7, 10-12, 18-20 and 23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Brenner (U.S. Patent No. 5,863,722, issued 26 January 1999).

Regarding Claim 1, Brenner discloses a composition comprising a substrate with a surface comprising discrete sites said sites separated by a distance of less than 50μm (i.e. separated by a space equal to microsphere diameter wherein the diameter of the microsphere is less than 50μ m (Column 10, lines 30-35 and Column 20, lines 32-35); and a population of microspheres comprising at least a first and second subpopulation wherein said first subpopulation comprises a first bioactive agent and said second subpopulation comprises a second bioactive agent wherein said microspheres are randomly distributed on said surface (Column 20, lines 42-46) wherein the substrate comprise the dimensions of a microscope slide (Column 19, lines 55-60 and Fig. 5).

Brenner et al specifically teach their microspheres are separated by a space (Column 20, lines 32-35). The instant specification defines "physical separation" as "spacing"(page 10, lines 3-5) and defines various preferred "partitions or borders" (page 10, lines 10-24). However, the specification does not define the instantly claimed "physical border". The claims are given the broadest reasonable interpretation consistent with the indefinite claim language and specification wherein "physical separation" is not defined. As such, the spacing between microspheres taught by Brenner is encompassed by the claimed physical separation.

The courts have stated that claims must be given their broadest reasonable interpretation consistent with the specification *In re Morris*, 127 F.3d 1048, 1054-55,

44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997); *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-551 (CCPA 1969); and *In re Zletz*, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) (see MPEP 2111).

Regarding Claim 2, Brenner discloses the composition wherein the sites are separated by a distance of less than 25 μ m (i.e. separated by a space equal to microsphere diameter wherein the diameter of the microsphere is less than 25μ m (Column 10, lines 30-35 and Column 20, lines 32-35).

Regarding Claim 3, Brenner discloses the composition wherein the sites are separated by a distance of less than 15 μ m (i.e. separated by a space equal to microsphere diameter wherein the diameter of the microsphere is less than 15μ m (Column 10, lines 30-35 and Column 20, lines 32-35).

Regarding Claim 4, Brenner discloses the composition wherein the sites are separated by a distance of at least about 5 μ m (i.e. separated by a space equal to microsphere diameter wherein the diameter of the microsphere is at least about 5μ m (Column 10, lines 30-35 and Column 20, lines 32-35).

Regarding Claim 6, Brenner discloses the composition wherein the distance between centers of a first and second subpopulations is at least 5 μ m (i.e. separated by a space equal to microsphere diameter wherein the diameter of the microsphere is at least about 5μ m (Column 10, lines 30-35 and Column 20, lines 32-35).

Regarding Claim 7, Brenner discloses the composition wherein the distance between a first and second microspheres is less than 100μ m (i.e. separated by a space equal to microsphere diameter wherein the diameter of the microsphere is less than 100μ m (Column 10, lines 30-35 and Column 20, lines 32-35).

Regarding Claim 10, Brenner discloses the composition wherein the distance between a first and second microspheres is less than 50μ m (i.e. separated by a space equal to

microsphere diameter wherein the diameter of the microsphere is less than 50μ m (Column 10, lines 30-35 and Column 20, lines 32-35).

Regarding Claim 11, Brenner discloses the composition wherein the distance between a first and second microspheres is less than 15μ m (i.e. separated by a space equal to microsphere diameter wherein the diameter of the microsphere is less than 15μ m (Column 10, lines 30-35 and Column 20, lines 32-35).

Regarding Claim 12, Brenner discloses the composition wherein the sites are separated by a distance of at least about 5 μ m (i.e. separated by a space equal to microsphere diameter wherein the diameter of the microsphere is at least about 5μ m (Column 10, lines 30-35 and Column 20, lines 32-35).

Regarding Claim 18, Brenner discloses a method for making a composition comprising a substrate with a surface comprising discrete sites said sites separated by a distance of less than 50μm (i.e. separated by a space equal to microsphere diameter wherein the diameter of the microsphere is less than 50μ m (Column 10, lines 30-35 and Column 20, lines 32-35); and a population of microspheres comprising at least a first and second subpopulation wherein said first subpopulation comprises a first bioactive agent and said second subpopulation comprises a second bioactive agent wherein said microspheres are randomly distributed on said surface (Column 20, lines 42-46) wherein the substrate comprise the dimensions of a microscope slide (Column 19, lines 55-60 and Fig. 5).

Regarding Claim 19, Brenner discloses the method wherein the sites are separated by a distance of less than 25 μ m (i.e. separated by a space equal to microsphere diameter wherein the diameter of the microsphere is less than 25μ m (Column 10, lines 30-35 and Column 20, lines 32-35).

Regarding Claim 20, Brenner discloses the method wherein the sites are separated by a distance of less than 15 μ m (i.e. separated by a space equal to microsphere diameter wherein

the diameter of the microsphere is less than 15μ m (Column 10, lines 30-35 and Column 20, lines 32-35).

Regarding Claim 23, Brenner discloses the composition wherein the distance between centers of a first and second subpopulations is at least 5 μ m (i.e. separated by a space equal to microsphere diameter wherein the diameter of the microsphere is at least about 5μ m (Column 10, lines 30-35 and Column 20, lines 32-35).

Regarding Claim 24, Brenner discloses the composition wherein the distance between centers of a first and second subpopulations is at least 15 μ m (i.e. separated by a space equal to microsphere diameter wherein the diameter of the microsphere is at least about 15μ m (Column 10, lines 30-35 and Column 20, lines 32-35).

Regarding Claim 25, Brenner discloses the method wherein the distance between a first and second microsphere is at least 50 μ m (i.e. separated by a space equal to microsphere diameter wherein the diameter of the microsphere is less than 50μ m (Column 10, lines 30-35 and Column 20, lines 32-35).

Response to Arguments

6. Applicant argues that Brenner does not teach physical borders that separate assay locations. The argument has been considered but is not found persuasive because as cited above, Brenner clearly teaches the broadly claimed physical borders as discussed above.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1-4, 6-7, 10-12, 18-20 and 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brenner (U.S. Patent No. 5,863,722, issued 26 January 1999) in view of McGall et al (U.S. Patent No. 6,147,205, filed 5 March 1997) and Brown et al (U.S. Patent No. 5,807,522, filed 7 June 1995).

The claims are rejected below as being drawn to Applicant's narrow interpretation of the physical separation.

Regarding Claim 1, Brenner discloses a composition comprising a substrate with a surface comprising discrete sites said sites separated by a distance of less than 50μm (i.e. separated by a space equal to microsphere diameter wherein the diameter of the microsphere is less than 50μ m (Column 10, lines 30-35 and Column 20, lines 32-35); and a population of microspheres comprising at least a first and second subpopulation wherein said first subpopulation comprises a first bioactive agent and said second subpopulation comprises a second bioactive agent wherein said microspheres are randomly distributed on said surface (Column 20, lines 42-46) wherein the substrate comprise the dimensions of a microscope slide (Column 19, lines 55-60 and Fig. 5).

Brenner et al specifically teach their microspheres are separated by a space (Column 20, lines 32-35) which clearly suggests a physical barrier between the assay regions. Physical barriers separating microspheres were well known in the art at the time the claimed invention was made as taught by McGall et al (Column 5, lines 33-36) and Brown et al provides the motivation to provide physical barriers between assay locations wherein they teach that physical barriers prevent cross-contamination between assay regions (Column 12, lines 52-56 and Column 15, lines 30-34).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the physical barriers of McGall et al and Brown et al to the microsphere spacing taught by Brenner for the expected benefit of preventing cross-contamination between the assay regions as taught by Brown et al (Column 12, lines 52-56 and Column 15, lines 30-34).

Regarding Claim 2, Brenner discloses the composition wherein the sites are separated by a distance of less than 25 μ m (i.e. separated by a space equal to microsphere diameter wherein the diameter of the microsphere is less than 25μ m (Column 10, lines 30-35 and Column 20, lines 32-35).

Regarding Claim 3, Brenner discloses the composition wherein the sites are separated by a distance of less than 15 μ m (i.e. separated by a space equal to microsphere diameter wherein the diameter of the microsphere is less than 15μ m (Column 10, lines 30-35 and Column 20, lines 32-35).

Regarding Claim 4, Brenner discloses the composition wherein the sites are separated by a distance of at least about 5 μ m (i.e. separated by a space equal to microsphere diameter wherein the diameter of the microsphere is at least about 5μ m (Column 10, lines 30-35 and Column 20, lines 32-35).

Regarding Claim 6, Brenner discloses the composition wherein the distance between centers of a first and second subpopulations is at least 5 μ m (i.e. separated by a space equal to microsphere diameter wherein the diameter of the microsphere is at least about 5μ m (Column 10, lines 30-35 and Column 20, lines 32-35).

Regarding Claim 7, Brenner discloses the composition wherein the distance between a first and second microspheres is less than 100μ m (i.e. separated by a space equal to microsphere diameter wherein the diameter of the microsphere is less than 100μ m (Column 10, lines 30-35 and Column 20, lines 32-35).

Regarding Claim 10, Brenner discloses the composition wherein the distance between a first and second microspheres is less than 50μ m (i.e. separated by a space equal to microsphere diameter wherein the diameter of the microsphere is less than 50μ m (Column 10, lines 30-35 and Column 20, lines 32-35).

Regarding Claim 11, Brenner discloses the composition wherein the distance between a first and second microspheres is less than 15μ m (i.e. separated by a space equal to microsphere diameter wherein the diameter of the microsphere is less than 15μ m (Column 10, lines 30-35 and Column 20, lines 32-35).

Regarding Claim 12, Brenner discloses the composition wherein the sites are separated by a distance of at least about 5 μ m (i.e. separated by a space equal to microsphere diameter wherein the diameter of the microsphere is at least about 5μ m (Column 10, lines 30-35 and Column 20, lines 32-35).

Regarding Claim 18, Brenner discloses a method for making a composition comprising a substrate with a surface comprising discrete sites said sites separated by a distance of less than 50μm (i.e. separated by a space equal to microsphere diameter wherein the diameter of the microsphere is less than 50μ m (Column 10, lines 30-35 and Column 20, lines 32-35); and a population of microspheres comprising at least a first and second subpopulation wherein said first subpopulation comprises a first bioactive agent and said second subpopulation comprises a second bioactive agent wherein said microspheres are randomly distributed on said surface (Column 20, lines 42-46) wherein the substrate comprise the dimensions of a microscope slide (Column 19, lines 55-60 and Fig. 5).

Brenner et al specifically teach their microspheres are separated by a space (Column 20, lines 32-35) which clearly suggests a physical barrier between the assay regions. Physical barriers separating microspheres were well known in the art at the time the claimed invention was made as taught by McGall et al (Column 5, lines 33-36) and Brown et al provides the motivation to provide physical barriers between assay locations wherein they teach that

physical barriers prevent cross-contamination between assay regions (Column 12, lines 52-56 and Column 15, lines 30-34).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the physical barriers of McGall et al and Brown et al to the microsphere spacing taught by Brenner for the expected benefit of preventing cross-contamination between the assay regions as taught by Brown et al (Column 12, lines 52-56 and Column 15, lines 30-34).

Regarding Claim 19, Brenner discloses the method wherein the sites are separated by a distance of less than 25 μ m (i.e. separated by a space equal to microsphere diameter wherein the diameter of the microsphere is less than 25μ m (Column 10, lines 30-35 and Column 20, lines 32-35).

Regarding Claim 20, Brenner discloses the method wherein the sites are separated by a distance of less than 15 μ m (i.e. separated by a space equal to microsphere diameter wherein the diameter of the microsphere is less than 15μ m (Column 10, lines 30-35 and Column 20, lines 32-35).

Regarding Claim 23, Brenner discloses the composition wherein the distance between centers of a first and second subpopulations is at least 5 μ m (i.e. separated by a space equal to microsphere diameter wherein the diameter of the microsphere is at least about 5μ m (Column 10, lines 30-35 and Column 20, lines 32-35).

Regarding Claim 24, Brenner discloses the composition wherein the distance between centers of a first and second subpopulations is at least 15 μ m (i.e. separated by a space equal to microsphere diameter wherein the diameter of the microsphere is at least about 15μ m (Column 10, lines 30-35 and Column 20, lines 32-35).

Regarding Claim 25, Brenner discloses the method wherein the distance between a first and second microsphere is at least 50 μ m (i.e. separated by a space equal to microsphere

diameter wherein the diameter of the microsphere is less than 50μ m (Column 10, lines 30-35 and Column 20, lines 32-35).

Response to Arguments

9. Applicant argues that Brenner does not teach physical borders that separate assay locations. The argument has been considered but is not found persuasive because as cited above, Brenner clearly teaches the broadly claimed physical borders as discussed above.

10. Claims 1-4, 6-7, 10-12, 18-20 and 23-25 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walt et al (U.S. Patent No. 6,327,410, filed 11 September 1998) in view of Noonan et al (U.S. Patent No. 6,129,896, filed 17 December 1998) and Van Ness et al (U.S. Patent No. 6,248,521, issued 19 June 2001).

Regarding Claim 1, Walt et al teach a composition comprising a substrate with a surface comprising discrete sites said sites separated by a distance of less than 50μ (Fig. 5); and a population of microspheres comprising at least a first and second subpopulation wherein said first subpopulation comprises a first bioactive agent and said second subpopulation comprises a second bioactive agent wherein said microspheres are randomly distributed on said surface (Column 4, lines 35-58) wherein the surface comprises assay locations (i.e. wells) separated from each other by a physical border (Column 5, lines 49-Column 6, lines 41 and Fig. 5). Walt et al teach that the substrate is configured for optimal observation via known microscope apparatus (Column 5, lines 55-57)) but they do not specifically teach their substrate comprises the dimensions of a microscope slide. However, it was well known in the art at the time the claimed invention was made that fiber optic bundles can be formatted to desired dimensions as taught by Noonan et al. (Abstract) and Van Ness et al teach a

motivation for formatting the substrate to have the dimensions of a microscope slide i.e. a substrate having the dimensions of a glass slide is easily illuminated and detected using a microscope (Column 10, lines 27-41). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the glass slide dimensioned substrate of Van Ness et al to the substrate of Walt et al and to format the substrate comprising microspheres to the format of a glass slide for the obvious benefits of facility of illumination and detection using a microscope as taught by Van Ness et al (Column 10, lines 27-41).

The courts have stated that claimed dimensions of a known device do not distinguish over the prior art device when the claimed device would not perform differently from the prior art device. *In Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.

The courts have stated that absent evidence to the contrary, a particular configuration of a known device is a matter of choice which would have been obvious to one skilled in the art. *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966) (The court held that the configuration of the claimed disposable plastic nursing container was a matter of choice which a person of ordinary skill in the art would have found obvious absent persuasive evidence that the particular configuration of the claimed container was significant.).

Regarding Claim 2, Walt et al teach the composition wherein the sites are separated by a distance of less than 25 μ m (Fig. 5).

Regarding Claim 3, Walt et al teach the composition wherein the sites are separated by a distance of less than 15 μ m (Fig. 5).

Regarding Claim 4, Walt et al teach the composition wherein said sites are separated by a distance of less than 15μ m (Fig. 5) but they do not teach the separation is at least 5μ m. However, It would have been obvious to one of ordinary skill in the art at the time the claimed

invention was made to modify the separation distance of Walt et al using routine experimentation to thereby derive an optimal separation distance (e.g. at least 5m m) for the obvious benefits of optimizing experimental conditions to thereby maximize experimental results.

It is noted that *In re Aller*, 220 F.2d 454,456, 105 USPQ 233,235 states where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum by routine experimentation.

Regarding Claim 6, Walt et al teach the composition wherein the distance between centers (i.e. pitch) of a first and second subpopulations is at least 5 μ m (Fig. 5).

Regarding Claim 7, Walt et al teach the composition wherein the distance between a first and second microspheres is less than 100μ m (Fig.5).

Regarding Claim 10, Walt et al teach the composition wherein the distance between a first and second microsphere is less than 50μ m (Fig. 5).

Regarding Claim 11, Walt et al teach the composition wherein the distance between a first and second microsphere is less than 15μ m (Fig. 5).

Regarding Claim 12, Walt et al teach the composition wherein the distance between centers of a first and second subpopulations is at least 2.2m m (Fig. 5) but they do not specifically teach the distance between the microspheres is at least 5μ m. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the distance between centers of the first and second subpopulations on the substrate of Walt et al using routine experimentation to thereby derive an optimal center-to-center distance (e.g. at least 5μ m) for the obvious benefits of optimizing experimental conditions to thereby maximize experimental results.

Regarding Claim 18, Walt et al teach a method for making a composition comprising: providing a substrate with a surface comprising discrete sites said sites separated by a distance of less than 50μm (Fig. 5); and randomly distributing a population of microspheres

comprising at least a first and second subpopulation wherein said first subpopulation comprises a first bioactive agent and said second subpopulation comprises a second bioactive (Column 27, lines 30-60). Walt et al teach that the substrate is configured for optimal observation via their microscope objective lens (Column 5, lines 55-57) but they do not teach their substrate comprises the dimensions of a microscope slide. However, it was well known in the art at the time the claimed invention was made that fiber optic bundles can be formatted to desired dimensions as taught by Noonan et al. (Abstract) and Van Ness et al teach a motivation for formatting the substrate to have the dimensions of a microscope slide i.e. a substrate having the dimensions of a glass slide is easily illuminated and detected using a microscope (Column 19, lines 27-41). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the glass slide dimensioned substrate of Van Ness et al to the substrate of Walt et al and to format the substrate comprising microspheres to the format of a glass slide for the obvious benefits of facility of illumination and detection using a microscope as taught by Van Ness et al (Column 19, lines 27-30).

The courts have stated that claimed dimensions of a known device do not distinguish over the prior art device when the claimed device would not perform differently from the prior art device. *In Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.

The courts have stated that absent evidence to the contrary, a particular configuration of a known device is a matter of choice which would have been obvious to one skilled in the art. *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966) (The court held that the configuration of the claimed disposable plastic nursing container was a matter of choice which a person of ordinary skill in the art would have found obvious absent persuasive evidence that the particular configuration of the claimed container was significant.).

Regarding Claim 19, Walt et al teach the method wherein said wells are separated by distance of less than 25μ m (Fig. 5).

Regarding Claim 20, Walt et al teach the method wherein said wells are separated by distance of less than 15μ m (Fig. 5).

Regarding Claim 23, Walt et al teach the composition wherein the distance between centers (i.e. pitch) of a first and second subpopulations is at least 5 μ m (Fig. 5).

Regarding Claim 24, Walt et al teach the method wherein the distance between centers of a first and second subpopulations is at least 5μ m (Fig. 5) but they do not specifically teach the distance between centers is at least 15μ m. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the distance between centers of the first and second subpopulations on the substrate of Walt et using routine experimentation to thereby derive an optimal center-to-center distance (e.g. at least 5m m and at least 15m m) for the obvious benefits of optimizing experimental conditions to thereby maximize experimental results.

It is noted that *In re Aller*, 220 F.2d 454,456, 105 USPQ 233,235 states where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum by routine experimentation.

Regarding Claim 25, Walt et al teach the method wherein the distance between microspheres is at least 5μ m (Fig. 5) but they do not specifically teach the distance between microspheres is at least 50m m. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the distance between microspheres on the substrate of Walt using routine experimentation to thereby derive an optimal distance (e.g. at least 50m m) for the obvious benefits of optimizing experimental conditions to thereby maximize experimental results.

It is noted that *In re Aller*, 220 F.2d 454,456, 105 USPQ 233,235 states where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum by routine experimentation.

Regarding Claim 27, Walt et al teach the method wherein the discrete sites are wells (page 7, lines 5-9).

Response to Arguments

11. Applicant argues that the Office has not cited a teaching of multiple assay locations separated by a physical border. The argument has been considered but is not found persuasive because as cited above, Walt et al clearly illustrates physical borders between the microspheres at Fig. 5.

Applicant states that the instantly claimed borders are used to prevent samples applied to one region from mixing with other assay regions and the cited art does not teach this utility. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., prevention of reagent mixing) is not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

12. Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walt et al (U.S. Patent No. 6,327,410, filed 11 September 1998) in view of Noonan et al (U.S. Patent No. 6,129,896, filed 17 December 1998) and Van Ness et al (U.S. Patent No. 6,248,521, issued 19 June 2001) as applied to Claim 18 above and further in view of Gentalen et al (U.S. Patent No. 6,306,643 B1, filed 24 August 1998).

Regarding Claims 21 and 22, Walt et al is silent regarding a ratio between microsphere subpopulations. However, ratios of subpopulations were well known in the art at the time the claimed invention was made as taught by Gentalen et al who teach that subpopulation ratios are derived based on experimental design (Column 11, lines 13-44 and Claim 9). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the ratio of first and second subpopulations based on experimental design to thereby optimize experimental results. For example, for an experiment designed to detect nucleic acid sequences expressed in low copy number, the skilled practitioner in the art would have been motivated to provide subpopulations of nucleic acid microspheres in a ratio of 1:36 or 1:100 (high copy number sequence:low copy number sequence) to thereby detect the low copy number sequence without signal interference from the high copy number sequence. In this experimental design it would have been obvious to one of ordinary skill in the art to modify the low copy to high copy number ratio using routine experimentation to thereby optimize experimental conditions and to maximize detection of low copy number.

13. Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brenner (U.S. Patent No. 5,863,722, issued 26 January 1999) in view of Gentalen et al (U.S. Patent No. 6,306,643 B1, filed 24 August 1998).

Regarding Claims 21 and 22, Brenner teaches the method for making a composition comprising a substrate with a surface comprising discrete sites said sites separated by a distance of less than 50μm (i.e. separated by a space equal to microsphere diameter wherein the diameter of the microsphere is less than 50μ m (Column 10, lines 30-35 and Column 20, lines 32-35); and a population of microspheres comprising at least a first and second

subpopulation wherein said first subpopulation comprises a first bioactive agent and said second subpopulation comprises a second bioactive agent wherein said microspheres are randomly distributed on said surface (Column 20, lines 42-46) wherein the substrate comprise the dimensions of a microscope slide (Column 19, lines 55-60 and Fig. 5). Brenner is silent regarding a ratio between microsphere subpopulations. However, ratios of subpopulations were well known in the art at the time the claimed invention was made as taught by Gentalen et al who teach that subpopulation ratios are derived based on experimental design (Column 11, lines 13-44 and Claim 9). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the ratio of first and second subpopulations based on experimental design to thereby optimize experimental results. For example, for an experiment designed to detect nucleic acid sequences expressed in low copy number, the skilled practitioner in the art would have been motivated to provide subpopulations of nucleic acid microspheres in a ratio of 1:36 or 1:100 (high copy number sequence:low copy number sequence) to thereby detect the low copy number sequence without signal interference from the high copy number sequence. In this experimental design it would have been obvious to one of ordinary skill in the art to modify the low copy to high copy number ratio using routine experimentation to thereby optimize experimental conditions and to maximize detection of low copy number.

Double Patenting

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 1-4, 6-7, 10-12, 18-25 and 27 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24 of Allowed Application No. 09/931,271. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to array compositions and methods of making same. The claim sets differ in the arrangement of limitations within the two claim sets. For example, instant independent Claim 1 is drawn to a substrate having the dimensions of a microscope slide wherein assay locations are separated by a physical border while dependent Claim 4 of the patent claim set requires a substrate having the dimensions of a microscope slide and dependent Claims 6-10 requires physical borders. The claim sets further differ in that the patent claims are drawn to a rigid support, a molded layer and an adhesive layer between the support and molded layer. However, the open claim language "comprising" recited in the instant claim encompasses the additional elements of the patent claims. Hence, the instant claims are not patentably distinct from the '271 claims.

Conclusion

16. No claim is allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BJ Forman, Ph.D.
Primary Examiner
Art Unit: 1634
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